

**REMARKS**

This Application has been carefully reviewed in light of the Final Office Action mailed May 17, 2006, and the Advisory Action mailed August 7, 2006. At the time of the Final Office Action and Advisory Action, Claims 138-148 were pending in this Application. Claims 138-140 and 142-148 were rejected and Claim 141 was objected to. Upon clarification during a telephone conference with Examiner Shibuya on August 17, 2006, the Examiner indicated that claim 141 stood rejected.

Claim 138 has been amended to recite the Markush group of Claim 141. Claim 139 has been amended to correct a typographical error. Claims 138 and 148 have been amended to recite "at least one alkali." New claims 154 and 155 have been added. Claim 141 has been cancelled. Applicant respectfully requests reconsideration and favorable action in this case.

The Advisory Action indicated that Applicant should identify where the specification discloses compositions that are free of any precipitates as claimed, for example, by claims 152 and 153. In response, Applicants invite the Examiner's attention to the following.

- Page 18, Lines 10-15 ("...which does not form a precipitate...")
- Page 19, Lines 8-9 ("It is an advantage of this invention that the bile acid and the carbohydrate remain in solution without precipitation at any pH from acidic to alkaline.")
- Page 19, Lines 9-10 ("These aqueous solution systems of bile acid are substantially free of precipitate or particles.")
- Page 25, Lines 5-8 ("The selected pH range for which the formulation will not precipitate its bile acid, starch conversion product, soluble non-starch polysaccharide or its pharmaceutical compound may be any range of pH levels obtainable with an aqueous system.")
- Page 30, Line 22 to Page 31, Line 1 ("Particularly, all solution formulations which contained bile acid showed excellent results in the stability tests with no precipitation and no physical appearance changes over the test period.")
- Page 32, Lines 10-11 ("Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH tested.")
- Page 39, Lines 2-4 ("Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected, desired range of pH values.")
- Page 47, Lines 2-3 ("Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected, desired pH range.")

Page 52, Lines 2-3 (“Solution dosage forms that were prepared according to the following guidelines did not show any precipitation at any pH within the selected desired range of pH values.”)

Page 90, Lines 1-3 (“Compositions for pharmaceutical and other uses comprising clear aqueous solutions of bile acids which do not form any detectable precipitates over selected ranges of pH values of the aqueous solution and methods of making such solutions.”)

Additional support may be found throughout the specification (e.g., Detailed Description, Examples, and Abstract.

Claims 138 and 148 have been amended to recite “at least one alkali.” Support for these amendments may be found throughout the specification, for example, at Page 28, Lines 12-14 (“The invention contemplates the use of pH adjustable agents. Non-limiting examples include ... alkalies.”)

Applicant respectfully requests entry of the Response to Office Action filed on July 17, 2006. For at least the reasons stated therein, the claims are believed to be in condition for allowance. In addition, Applicant respectfully asserts that none of the cited references, either alone or in combination, teaches or suggests at least one alkali.

#### **Request for Continued Examination (RCE)**

Applicant encloses a Request for Continued Examination (RCE) Transmittal.

#### **CONCLUSION**

Applicant has now made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicant respectfully requests reconsideration of the pending Claims.

Applicant believes that a fee of \$395.00 for the RCE, and a fee of \$60.00 for a Petition for Extension of Time are due, however, the Commissioner is hereby authorized to charge to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at (512) 322-2647.

Respectfully submitted,  
BAKER BOTTS, L.L.P.  
Attorneys for Applicant



Guy F. Birkenmeier  
Reg. No. 52,622

Date: September 18, 2006

CORRESPONDENCE ADDRESS:

Customer No. **31625**

(512) 322-2647  
(512) 322-8383 FAX

Enclosures:   1)     RCE transmittal form  
                  2)     Petition For Extension of Time (One Month)